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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,931	08/27/2003	Jong-Soo Woo	DE-1500	8064
1109 7590 11/30/2007 ANDERSON, KILL & OLICK, P.C. 1251 AVENUE OF THE AMERICAS NEW YORK, NY 10020-1182			EXAMINER SPIVACK, PHYLLIS G	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 11/30/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/650,931	Applicant(s) WOO ET AL.	
	Examiner Phyllis G. Spivack	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,6 and 8-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,6 and 8-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

An indication of finality set forth in the last Office Action is withdrawn.

Applicants' Amendment filed October 24, 2007 is acknowledged. Claims 1, 5, 6 and 8-10 remain under consideration. The subject matter under consideration remains those sustained-release compositions for oral administration comprising the drug nifedipine, a mixture of sodium alginate and xanthan gum, representing the carrier for sustained release of nifedipine, and a mixture of hydroxypropyl methylcellulose and propylene glycol alginate, representing the gel hydration accelerator.

Those compositions comprising other drugs, carriers and gel hydration accelerators remain withdrawn from consideration by the Examiner as drawn to non-elected inventions.

Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejection is newly applied. It constitutes the only rejection presently applied to the instant application.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5, 6 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al., U.S. Patent 6,264,981, in view of Baichwal, A.R., U.S. Patent 5,846,563.

Zhang teaches sustained-release compositions for oral administration comprising nifedipine. See column 16, claims 22-24, where the dosage forms may be an oral transmucosal patch, a lozenge/troche, a lollipop or a chewing gum. See claim 28, where nifedipine is

specifically disclosed as a pharmaceutical agent encompassed in Zhang's teaching. As required by instant claim 8, non-steroidal anti-inflammatory agents and antibiotics are further encompassed in Zhang's disclosure. See column 6, lines 51-53. Zhang teaches sodium alginate, xanthan gum, hydroxypropyl methylcellulose and propylene glycol alginate are ingredients that may be formulated with a drug for oral administration. Zhang provides a mechanism of controlling drug release by controlling dissolution and disintegration. Although a mixture of hydroxypropyl methylcellulose and propylene glycol alginate are characterized as "the gel hydration accelerator" and the mixture of sodium alginate and xanthan gum are characterized as "the carrier" in instant claims 1 and 10, these four compounds are characterized by Zhang as "dissolution agents." However, Baichwal teaches a combination of a gelling agent and an inert diluent, i.e., a mixture of xanthan gum and locust bean gum, with or without a cross-linking agent and hydrophilic polymer, i.e., hydroxypropylmethylcellulose, provides a product to which the desired active medicament (nifedipine) is physically admixed. See column 8, lines 19-27. The bioavailability of nifedipine, a poorly soluble drug, is thus increased. The open language of the present claims allows for the inclusion of any number of additional active or inactive agents.

With respect to claimed weight ratios as recited in instant claims 1, 6 and 10, it is not inventive to discover the optimum or workable ranges by routine experimentation when general conditions of a claim are disclosed in the prior art. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955) and MPEP 2144.05(II). The determination of the optimum ratio to employ with the presently claimed active and inactive agents would have been a matter well within the purview of one of ordinary skill in the art. Such determination would have been made in accordance with a variety of factors. These would have included such factors as the age,

weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered a part of a drug combination. Thus, in the absence of evidence to the contrary, the currently claimed specific proportions of the claimed ingredients are not seen to be inconsistent with the ratios that would have been determined by the skilled artisan in formulation chemistry.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number:
10/650,931
Art Unit: 1614

Page 5

Phyllis Spivack

Phyllis Spivack

**PHYLLIS SPIVACK
PRIMARY EXAMINER**

November 27, 2007